

Amendments to the Claims:

This listing of the claims replaces all prior versions, and listings, of claims in the present application:

Listing of the Claims:

1. (Currently Amended) An orally deliverable pharmaceutical once daily sustained release composition comprising ~~a therapeutically effective amount about 0.1 to about 10 mg of~~ pramipexole dihydrochloride monohydrate ~~or a pharmaceutically acceptable salt thereof~~ a starch in an amount of about 25% to about 75 % by weight, a hydrophilic polymer in an amount of about 20% to about 70% by weight, wherein said pramipexole is dispersed in hydrophilic polymer and starch, and said hydrophilic polymer functions to provide sustained release of said pramipexole ~~and at least one pharmaceutically acceptable excipient~~, said composition exhibiting at least one of (a) an in vitro release profile wherein on average no more than about 20% of the pramipexole is dissolved within 2 hours after placement of the composition in a standard dissolution test conducted according to USP24 using Apparatus 1 with a spindle rotation speed of 100 rpm and a dissolution medium of 0.05M phosphate buffer, pH 6.8, at 37°C; and (b) an in vivo pramipexole absorption profile following single dose oral administration to healthy adult humans wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours wherein said composition comprises a full daily dose contained in a single dose unit, further wherein said composition, when administered once daily, exhibits a bioavailability substantially equivalent to an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation administered three times a day.
2. (Cancelled)
3. (Currently Amended) The composition of claim 1 wherein no more than about 12% of the pramipexole dihydrochloride monohydrate dissolves within 1 hour in said test.
4. (Previously Presented) The composition of claim 1 wherein time to reach 50% dissolution is at least about 4 hours.
5. (Previously Presented) The composition of claim 1 wherein time to reach 50% dissolution is at least about 6 hours.

6. (Previously Presented) The composition of Claim 1 wherein time to reach 50% dissolution is at least about 8 hours.
7. (Previously Presented) The composition of Claim 1 wherein time to reach 50% dissolution is at least about 12 hours.
8. (Original) The composition of claim 1 that exhibits an in vivo pramipexole absorption profile following single dose oral administration to healthy adult humans wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours.
9. (Original) The composition of claim 8 wherein the time to reach a mean of 40% absorption is at least about 5 hours.
10. (Original) The composition of claim 8 wherein the time to reach a mean of 40% absorption is at least about 6 hours.
11. (Cancelled)
12. (Original) The composition of claim 1 that, following single dose administration of 0.375 mg, expressed as pramipexole dihydrochloride monohydrate equivalent, exhibits a maximum plasma concentration (C_{max}) of pramipexole that is not greater than about 0.3 ng/ml.
13. (Original) The composition of claim 1 that exhibits a time to reach maximum plasma concentration (T_{max}) of pramipexole that is at least about 6 hours following administration of the composition.
14. (Original) The composition of claim 1 that exhibits a time to reach maximum plasma concentration (T_{max}) of pramipexole that is at least about 8 hours following administration of the composition.
15. (Original) The composition of claim 1 that exhibits a pharmacokinetic profile consistent with steady-state plasma concentrations having a fluctuation ratio that is not substantially greater than that of an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation, administered three times a day.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Cancelled)

20. (Original) The composition of claim 1 that is in the form of discrete dosage units.

21. (Cancelled)

22. (Cancelled)

23. (Cancelled)

24. (Original) The composition of claim 20 that comprises about 0.2 to about 6 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

25. (Original) The composition of claim 20 that comprises about 0.3 to about 5 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

26. (Withdrawn) A method of treatment of a subject having a condition or disorder for which a dopamine receptor agonist is indicated, the method comprising orally administering to the subject, not more than once daily, the composition of claim 1.

27. (Withdrawn) The method of claim 26 wherein the condition or disorder is Parkinson's disease or a complication associated therewith.

28. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 0.375mg.

29. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 0.5mg.

30. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 0.75mg.
31. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 1.0mg.
32. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 1.5mg.
33. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 3.0mg.
34. (New) The composition according to claim 1, wherein the amount of pramipexole dihydrochloride monohydrate is 4.5mg.
35. (New) The composition according to claim 1, wherein the amount of starch is about 40% to about 70% by weight.
36. (New) The composition according to claim 1, wherein the amount of starch is about 45% to about 65% by weight.
37. (New) The composition according to claim 1, wherein the amount of the hydrophilic polymer is about 30% to about 60% by weight.
38. (New) The composition according to claim 1, wherein the amount of the hydrophilic polymer is about 35% to about 60% by weight.
39. (New) The composition according to claim 1, wherein the amount of the hydrophilic polymer is about 35% to about 50% by weight.
40. (New) The composition according to claim 1 in the form of a tablet.
41. (New) The composition of claim 1 that exhibits an in vitro release profile wherein on average no more than about 20% of the pramipexole is dissolved within 2 hours after placement

of the composition in a standard dissolution test conducted according to USP24 using Apparatus I with a spindle rotation speed of 100 rpm and a dissolution medium of 0.05M phosphate buffer, pH 6.8, at 37°C.